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EXAMINER	
STEELE, AMBER D	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Continued

Withdrawn Rejection

The rejection under 35 USC 112, first paragraph (new matter), for claims 1-11, 13-14, 17-18, 21, 24, and 26-27 is withdrawn in view of applicants response regarding paragraph 51 of the PGPub (i.e. page 14, lines 21-27 of the originally filed specification). It is noted that copies of Exhibits C-E were not received.

Arguments and Response

Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Minden et al. and Nelson et al. for claims 1-11, 13-14, 17-18, 21, 24, and 26-27 were considered but are not persuasive for the following reasons.

Applicants contend that the central idea of Minden et al. is to "apply a peptide mixture generated by digestion of a sample containing a single protein, not a mixture of proteins, with the aim of identifying that protein". Applicants also contend that the disclosure in Minden et al. at paragraphs 35 and 66 discusses protein mixture, but not in the context of samples to be analyzed using the described invention. Applicants contend that "the aim in Nelson et al. is not to separate unknown, complex samples into well-defined sub-classes prior to analysis but to combine known and used sample preparation techniques…with mass spectrometry". In addition, applicants contend that the presently claimed invention is drawn to analysis with "no advanced knowledge of the identity of individual proteins in a protein sample is required in order to perform the method of the present invention". Applicants further contend that "a person skilled in the art would normally avoid and argue against using affinity reagents (e.g. antibodies) that bind to

heterogenous proteins, peptides, or peptide fragments as mono-specific binding reagents…are normally used".

Applicants' arguments are not convincing since the teachings of Minden et al. and Nelson et la. render the method of the instant claims *prima facie* obvious.

It is noted that the present invention as claimed in drawn to a "method for analysing a heterogenous sample of proteins, peptides, protein fragments, or peptide fragments, the method comprising: (a) separating the heterogenous sample of proteins, peptides, protein fragments, or peptide fragments into heterogenous classes by binding members of each class to a spaced apart defined location on an array". Therefore, "a mixture of proteins" is not required by the claims but is one member of the Markush group presently claimed.

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). See MPEP § 2123. In addition, paragraph 35 of Minden et al. defines "protein mixture" and paragraph 66 teaches that "trypsin-digested yeast total protein is affixed to a surface…and binding reagent-displaying phage are absorbed on the surface…[d]igested total protein form any given protein mixture may be used…". Therefore, while the specific example in paragraph 66 refers to having the protein mixture on the array, one of skill in the art could envision either phage displaying the trypsin-digested yeast total protein or utilizing the phage displayed peptides on the support and adding in the protein mixture since the end result (e.g. screening for specific binding between the two groups of molecules) would be

the same. The claims would have been obvious because the substitution of one known element (i.e. protein mixture on a support, adding binding molecules to support comprising protein mixture taught by Minden et al.) for another (i.e. protein mixture free from support, added to support comprising binding molecules) would have yielded predictable results (i.e. screening for binding) to one of ordinary skill in the art at the time of the invention and/or (b) the claim would have been obvious because a particular known technique (i.e. binding molecules on support or free in solution and added to support to screen for binding) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. no previous knowledge of the composition of the peptides or proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, both arrays and polyclonal antibodies are well-known in the art (prior art references will be provided if requested by the applicants). Furthermore, the presently claimed invention is not currently drawn to a method of using a polyclonal antibody array. It is also noted

that the presently claimed invention states that the molecules on the array "is capable of binding specifically to a motif" (see present claim 13) and "the motif being constant between all peptides, or protein, or peptide fragments" (see present claim 10). Therefore, each discrete location on the array binds to the same motif. While the individual proteins or peptides in the heterogeneous sample may be different, each spot on the array binds to the same motif (i.e. the presently claimed invention is drawn to "mono-specific binding reagents" at each spot on the array wherein different spots comprise different binding reagents which is typical of arrays described in the prior art).

Arguments and Response

Applicant's argument directed to the rejection under 35 USC 103(a) as being unpatentable over Minden et al. WO 02/086081 A2 (filing date April 22, 2002) and Barry et al. WO 0225287 (filed September 19, 2001) for claims 1-11, 13-14, 17-18, 21, 24, and 26-27 was considered but was not persuasive for the following reasons.

Applicants contend that the central idea of Minden et al. is to "apply a peptide mixture generated by digestion of a sample containing a single protein, not a mixture of proteins, with the aim of identifying that protein". Applicants also contend that the disclosure in Minden et al. at paragraphs 35 and 66 discusses protein mixture, but not in the context of samples to be analyzed using the described invention. In addition, applicants contend that the presently claimed invention is drawn to analysis with "no advanced knowledge of the identity of individual proteins in a protein sample is required in order to perform the method of the present invention". Applicants further contend that "a person skilled in the art would normally avoid and argue

against using affinity reagents (e.g. antibodies) that bind to heterogenous proteins, peptides, or peptide fragments as mono-specific binding reagents…are normally used".

Applicant's argument is not convincing since the combined teachings of Minden et al. and Barry et al. do render the method of the instant claims *prima facie* obvious.
It is noted that the present invention as claimed in drawn to a "method for analysing a heterogenous sample of proteins, peptides, protein fragments, or peptide fragments, the method comprising: (a) separating the heterogenous sample of proteins, peptides, protein fragments, or peptide fragments into heterogenous classes by binding members of each class to a spaced apart defined location on an array". Therefore, "a mixture of proteins" is not required by the claims but is one member of the Markush group presently claimed.

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the same. The claims would have been obvious because the substitution of one known element (i.e. protein mixture on a support, adding binding molecules to support comprising protein mixture taught by Minden et al.) for another (i.e. protein mixture free from support, added to support comprising binding molecules) would have yielded predictable results (i.e. screening for binding) to one of ordinary skill in the art at the time of the invention and/or (b) the claim would have been obvious because a particular known technique (i.e. binding molecules on support or free in solution and added to support to screen for binding) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

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Description in the Specification

In order to further support the statement that "the presently claimed invention is drawn to "mono-specific binding reagents" at each spot on the array wherein different spots comprise different binding reagents which is typical of arrays described in the prior art", the originally filed specification teaches the following:

Page 10, lines 22-28 and page 11, lines 1-5: Typically the spots on the array comprises a number of different types of binding molecule (as defined below), each type being immobilised at a separate spot on the array. Thus by using a method of generating spots with defined locations, it is possible to know the identity and/or binding affinity of each spot on the array. Preferably, each type of binding molecule, and therefore, each spot, is capable of binding specifically to a defined motif as defined above and the different types of binding molecule have different binding specificities. Thus proteins, peptides and/or fragments thereof that bind to one spot will share a common motif. Conversely, proteins, peptides and/or fragments thereof on different spots are separated into heterogeneous classes based on the presence of different motifs.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Amber D. Steele/
Patent Examiner, Art Unit 1639

March 9, 2009